Supreme Court, U.S.
FILED
01 261 AUG 11 2001
OFFICE OF THE CLERK

No. 01-

IN THE

Supreme Court of the United States

CHARLES PHILIP AKIN,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

STEVEN JAY ROZAN
KUNIANSKY, KARAHAN & ROZAN
Attorneys for Petitioner
5051 Westheimer
Suite 700
Houston, Texas 77056
(713) 627-3608

168451

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

62 pp

QUESTIONS PRESENTED

1. Whether the retrospective application of a Social Security Administrative ruling interpreting vague definitions in the Social Security Act effective September 18, 1996 can be used as a basis for a criminal prosecution which was commenced on May 7, 1997 for alleged criminal conduct between November 1991 through July, 1993 constitutes an clear violation of the Due Process Clause of the Fifth Amendment to the Constitution of the United States.

2. Whether Petitioner was unconstitutionally sentenced under an increased offense level under the Federal Sentencing Guidelines based upon facts that were not included in the indictment nor proven at trial beyond a reasonable doubt.

TABLE OF CONTENTS

Page

Questions Presented i

Table of Contents ii

Table of Cited Authorities iv

Table of Appendices ix

Opinion Below 1

Statement of Jurisdiction 1

Constitutional Provisions, Statute and Regulation Involved 1

Statement of the Case 2

A. The Proceedings Below 2

B. The Relevant Facts 2

Reasons for Granting the Writ 8

A. In affirming the Petitioner's conviction, the United States Court of Appeals failed to address and rule upon an important substantive constitutional question- whether the retrospective application of an administrative ruling which imposed criminal liability on Petitioner is a clear violation of the Due Process Clause of the Fifth

Contents

Page

Amendment to the Constitution by criminalizing sanctioned conduct prior to the administrative ruling. 8

B. The Petitioner was unconstitutionally sentenced under an increased Offense Level of 29, based upon facts that were not included in the indictment nor proven at trial beyond a reasonable doubt. 18

Conclusion 21

TABLE OF CITED AUTHORITIES

Page

Cases:

Apprendi v. New Jersey, 530 U.S. 466, 120 S. Ct. 2348 (2000) 18, 19, 20, 21

Babbitt v. Sweet Home Chapter of Communities For A Great Oregon, 515 U.S. 687, 115 S. Ct. 2407 (1995) 8

Blue v. United States, 121 S. Ct. 32 (2000) 18

Bowen v. Georgetown University Hospital, 109 S. Ct. 468 (1988) 10

Brown v. United States, 2000 U.S. LEXIS 6603 .. 18

Burton v. United States, 121 S. Ct. 32 (2000) 18

Clinton v. United States, 2000 U.S. LEXIS 6605 .. 18

Curry v. United States, 121 S. Ct. 376 (2000) 18

Dunn v. United States, 442 U.S. 100 (1979) 17

Georgia Pacific Corp. v. OSHRC, 25 F.3d 999 (1994) 11

Gibson v. United States; 121 S. Ct. 31 (2000) 18

Grayned v. City of Rockford, 408 U.S. 104 (1972) .. 13, 16

Cited Authorities

	Page
Hester v. United States, 121 S. Ct. 336 (2000)	18
Hughes v. United States, 121 S. Ct. 423 (2000) ...	18
Humphrey v. United States, 121 S. Ct. 478 (2000) ..	18
In re OrthoConcepts v. MetraHealth, Dkt. No. 000-45-1375	9
Knight v. United States, 121 S. Ct. 478 (2000)	18
Kolender v. Lawson, 461 U.S. 352 (1983)	14
McMillan v. Pennsylvania, 477 U.S. 79 (1986) ...	20
Meais v. United States, 121 S. Ct. 559 (2000)	18
Potts v. United States, 121 S. Ct. 559 (2000)	18
Smith v. Goguen, 415 U.S. 566 (1974)	16
Smith v. United States, 121 S. Ct. 336 (2000)	18
Travis Randle v. United States, 2001 WL 81170 ..	18
Twitty v. United States, 121 S. Ct. 559 (2000)	18
United States v. Ferguson, 211 F.3d 878 (5th Cir. 2000)	12

Cited Authorities

Page

United States v. Garber, 607 F.2d 92 (5th Cir. 1979) 15, 17

United States v. Gaudin, 515 U.S. 506 (1995) 20

United States v. Gonzalez, __ F.3d __, 2001 WL 815606 19

United States v. Howard, 220 F.3d 645 (5th Cir. 2000) 12

United States v. Keller, 14 F.3d 1051 (5th Cir. 1994) 16

United States v. Lanier, 520 U.S. 259 (1997) 14

United States v. Marek, 238 F.3d 310 (5th Cir. February 2, 2001) 14

United States v. Meshack, 225 F.3d 556 (5th Cir. 2000) 20

United States v. Phillips, 600 F.2d 535 (5th Cir. 1979) 16

United States v. Reliford, 210 F.3d 285 (5th Cir. 2000) 12

United States v. Upton, 91 F.3d 677 (5th Cir. 1995) 11

Cited Authorities

Page

Warder v. Shalala, (1997 WL 263733, 1997 U.S. Dist. Lexis 7029) 9

Warder v. Shalala, 149 F.3d 73 (decided July 27, 1998) 10

Whitt v. United States, 121 S. Ct. 423 (2000) 18

Wims v. United States, 121 S. Ct. 32 (2000) 18

United States Constitution:

Fifth Amendment .....i, 1, 7, 8, 13, 15, 20

Sixth Amendment 1, 20

Statutes:

18 U.S.C. § 2 2

18 U.S.C. § 287 2

18 U.S.C. § 371 2

18 U.S.C. § 1341 2

18 U.S.C. § 1956(a)(1)(A)(i) 2

28 U.S.C. § 1254(1) 1

Cited Authorities

	Page
42 U.S.C. § 1395(e)(1)	4
42 U.S.C. § 1395i-3(a)(i)	4
42 U.S.C. § 1395x(5)(9)	1
42 U.S.C. § 1395x(n)	4
U.S.S.G. § 2S1.1	19
Rule:	
Fed. R. Crim. P. 29	12
Other Authorities:	
42 C.F.R. § 410.36(a)(3)	1
42 C.F.R. § 410.38(d)	3
42 C.F.R. § 410.100(g)(1)	1, 3

TABLE OF APPENDICES

Page

Appendix A — Per Curiam Opinion Of The United States Court Of Appeals For The Fifth Circuit Dated And Filed May 16, 2001 ..... 1a

Appendix B — Decision Of The Social Security Administration Office Of Hearings And Appeals In *Orthoconcepts v. Metrahealth* Dated January 3, 1996 ..... 4a

Appendix C — Ruling No. 96-1 Of The Department Of Health And Human Services, Health Care Financing Administration Dated September 18, 1996 ..... 14a

Appendix D — Excerpts From Memorandum And Recommendation Of United States Magistrate Judge Of The United States District Court For The Western District Of Texas, San Antonio Division Dated And Filed May 17, 1999 ..... 24a

Appendix E — Constitutional Provisions, Statute And Regulations Involved 28a

Petitioner prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Fifth Circuit entered in this case on May 16, 2001 affirming Petitioner's conviction and sentence.

OPINION BELOW

The opinion of the United States Court of Appeals for the Fifth Circuit is unreported, but is reproduced at Appendix A.

STATEMENT OF JURISDICTION

The United States Court of Appeals for the Fifth Circuit rendered its unpublished opinion on May 16, 2001 affirming the judgment and sentence entered on February 11, 2000 in the United States District Court for the Western District of Texas, San Antonio Division, Hon. H. F. Garcia presiding.

This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

CONSTITUTIONAL PROVISIONS, STATUTE AND REGULATION INVOLVED

This case involves the Fifth and Sixth Amendments to the United States Constitution, as well as 42 U.S.C. § 1395x(5)(9); 42 C.F.R. § 410.100(g)(1); and 42 C.F.R. § 410.36(a)(3). The pertinent portions of these can be found reproduced at Appendix E.

STATEMENT OF THE CASE

A. The Proceedings Below

Petitioner, Charles Philip Akin and two co-defendants, were charged on May 7, 1997 in an eighty-eight count indictment in the Western District of Texas, San Antonio Division, with a general conspiracy to commit fraud (18 U.S.C. § 371) multiple counts of mail fraud (18 U.S.C. §§ 1341 & 2) money laundering (18 U.S.C. § 1956(a)(1)(A)(i)) and submitting false claims (18 U.S.C. § 287).

On June 14, 1999, trial commenced, and on June 29, 1999 the jury returned verdicts of guilty on all counts. On February 24, 2000 Akin was sentenced to 87 months imprisonment to run concurrently on all counts. In addition, he was ordered to pay a special assessment totaling $3,650 and to make restitution of $1,108,775.90 to Medicare/ Medicaid. Petitioner filed a pre-trial Motion to Dismiss the indictment. After an evidentiary hearing the Magistrate Judge recommended denial of the Motion to Dismiss. Akin filed objections to the Report and Recommendation, which the trial court impliedly overruled when trial began.

On June 28, 2000, Petitioner self-surrendered without incident to the United States Marshal's Service. On July 17, 2000, he was transferred to FCI Bastrop in Bastrop, Texas, where he remains detained at the Federal Prison Camp.

B. The Relevant Facts

Charles Philip Akin is a sixty-six year old dentist from Austin, Texas, who was engaged in a medical supply business from 1991 to 1993. He invested $257,000 in a corporation,

BioTex, Inc., which was selling a body support product, for which the corporation had been receiving reimbursement from Medicare. Akin formed a corporation, Health Care of Texas, Inc., for the purpose of selling the product to nursing homes. Co-defendants Henderson and Gurasich sold the same product through an Austin-based business called Continental Health. Between February 1992 and June 1993 Akin submitted claims to the Medicare regional carrier, Blue Cross & Blue Shield of Texas (hereinafter "Blue Cross")[1] for body or lumbar supports used by nursing home residents confined to wheelchairs. The claims were for "orthotic devices," reimbursable by federal regulation, which describes them as "orthopedic devices that support or align movable parts of the body, prevent or correct deformities, or improve functioning." 42 C.F.R. § 410.100(g)(1).[2] Akin's device, which fitted into the wheelchair, had adjustable sides and front pads, rigid side and base inserts, was held by adjustable clasps and straps and used pads. It kept patients upright, aligning their spine and hips. Defense witness, Dr. David Abbott, who signed most of the certificates of medical necessity which accompanied Akin's claims, testified that wheelchair bound patients who could not maintain normal posture developed ulcers and other serious physical problems if not properly positioned in their chairs.

---

1. Blue Cross later became Texas/Trailblazer Health Enterprises.

2. "Durable medical equipment" is paid for under Part B of Medicare if it is medically necessary equipment used for treatment of decubitus ulcers, and it is ordered in writing by the beneficiary's physician, who will be supervising its use in the course of treatment. 42 C.F.R. § 410.38(d).

Akin submitted his claims to Blue Cross for a "lumbar-sacral support system," accompanied by a certificate of medical necessity which stated that the condition for which the device was needed was "patient is wheelchair confined with inability to maintain proper body alignment when sitting." Typical medical diagnoses on the certificates were "dementia," "Alzheimers," or "osteoarthritis." Akin's claims for reimbursement were made under Code L0430, which appears under the heading "Orthotics" in a Medicare Part B handbook on durable medical equipment for doctors and suppliers. Code L0430 is defined in the handbook as "TLSO, anterior-posterio-lateral control (body jacket), with interface material, custom fitted."[3] A device similar to that sold by Akin's company was marketed to the Veterans Administration by Akin's former associate, Bowman, who testified as a government witness. Other similar devices were routinely paid by Medicare carriers in other parts of the country.

Prior to Akin's investment in BioTex, Inc., the Health Care Finance Administration (HCFA) issued a letter stating that "custom designed orthotic *seating and positioning systems* . . . may be covered under Part B of the Medicare program." No official statement of the Department of Health and Human Services or HCFA regarding "orthotics" or "body jackets" was issued after that date until a "national policy" was publicly stated in September 1996, three years and three months after the last claim submitted by Akin which the government alleges was "fraudulent." This national policy

---

3. "TLSO" makes reference to "Thoracic Lumbar Sacral Orthotic." 42 U.S.C. § 1395x(n) provides that Medicare Part B precludes coverage of durable medical equipment used in a hospital (42 U.S.C. § 1395(e)(1)) or a skilled nursing facility (42 U.S.C. § 1395i-3(a)(i)).

stated that those terms applied only to rigid devices that tightly fit and immobilize the body, language not included previously in any regulation, directive, or guideline. This policy was issued after an Administrative Law Judge ruled on January 3, 1996 that equipment similar to Akin's which was used for wheelchair seating and body positioning constituted a reimbursable brace or orthotic. This holding was affirmed by a Medicare carrier appeals board. On February 9, 1996 a Medicare carrier hearing officer reached the same conclusion. These decisions were the first definitive statements of the law as to the interpretation of devices similar to Akin's.

The government contended that Akin committed fraud, however, by falsely claiming Between February 1992 and June 1993 that his devices were reimbursable "orthotic devices," billed under Code L0430, when they were in reality "non-orthotic medical equipment." The government contended that Akin knew that this was a false designation because in August 1992, after Akin had submitted and received payment for his devices from Blue Cross, the carrier published a newsletter in which it stated that Medicare had identified a product being billed under Code L0430 which "consist[ed] of a seat and back, is constructed of foam rubber covered by vinyl and held together with straps and Velcro." The newsletter claimed that Medicare had determined that the product did not meet the code definition in the handbook because it "represents a safety and postural device used in wheelchairs that is not covered by the Medicare program." Akin discussed this with the manufacturer of his product, who was satisfied that it did not describe the product he was making for Akin to distribute. Akin's device provided full body support, has adjustable sides and front pads, is made with rigid side and base inserts and is held by adjustable clasps and straps rather than Velcro. Subsequently, Blue Cross continued to pay Akin's claims until June 1993.

In late September 1993, Blue Cross adopted a "policy" stating that equipment claimed under Code L0430 must, among other things, "be used to immobilize the specified areas of the spine," and may "not [be] specifically designed for patients in wheelchairs." In 1994, after the last date of fraudulent billing alleged by the government, the Department of Health and Human Services conducted a study which *recommended* that Code L0430 be used only for rigid plastic devices not used in wheelchairs. The study acknowledged that Code L0430 provided only a "vague" and "general description," and that it contained loopholes which allowed suppliers to claim other devices as meeting the definition. The study was based in large part on interviews with orthotists and doctors who designed equipment which competed with equipment of the type sold by Akin.

The government produced witnesses at trial who rendered their opinion as to the applicability of Code L0430 to Akin's devices and testified to varying remarks from family members of patients. Dianne Cassen, a physical therapist, testified over objection that in her opinion that Akin was using the wrong code for his billing, that his product was durable medical equipment and that the product was not reimbursable. Her opinion was based in part on hearsay testimony that "Medicare" had told her that if a product is profitable quickly it is probably "not okay." Conrad Bowman, a former marketing associate of Akin's co-defendants who became a competitor by selling a similar device from Mississippi to the Veterans Administration, testified as to his opinion that L-Codes require an prescription by an orthotist (a medical specialist in orthotics). Over objection he testified that it would be fraud to bill Akin's device as a "body jacket." His testimony contrasted with the testimony of Dr. Rodney Carry, a nursing home physician, who testified

that he had been a physician for twenty years, but did not know what a "body jacket" is. He testified that the term "orthotic" was nonspecific, applicable to multiple devices which support a weak or injured body member. He also testified that Petitioner's exhibits D1 through D4 were, in his experience and training, orthotic devices.

Petitioner argued to the Court of Appeals that the underlying definitions of an orthotic device was void for vagueness and was in violation of the Fifth Amendment. The Court of Appeals gave short shrift to this argument stating the following:

> On appeal, Akin raises several points of error. First, he contends that the indictment should have been dismissed because the basis for those charges was a vague and indefinite Medicare claims code, which failed to give him fair notice of the illegality of his conduct. . . . we conclude that the district court did not commit reversible error with respect to the point[s] raised by Akin.

(*See* Appendix A.)

REASONS FOR GRANTING THE WRIT

A. In affirming the Petitioner's conviction, the United States Court of Appeals failed to address and rule upon an important substantive constitutional question- whether the retrospective application of an administrative ruling which imposed criminal liability on Petitioner is a clear violation of the Due Process Clause of the Fifth Amendment to the Constitution by criminalizing sanctioned conduct prior to the administrative ruling.

The case at bar presents an unusual and unique constitutional question which counsel believes has not been directly addressed by this Court in a federal criminal case.

This Court has spoken to the rule of lenity in *Babbitt v. Sweet Home Chapter of Communities For A Great Oregon*, 515 U.S. 687, 115 S. Ct. 2407 (1995) in the context of legislation and regulatory interpretation:

> . . . The rule of lenity is premised on two ideas: First, " 'a fair warning should be given to the world in language that the common world will understand, of what the law intends to do if a certain line is passed' "; second "legislatures and not courts should define criminal activity." [citing cases] . . . Even if there exists regulations whose interpretations of statutory criminal penalties provide such inadequate notice of potential liability as to offend the rule of lenity . . .

Id. at 704 n.18.

With this perspective of the rule of lenity, this Court should view the instant controversy regarding the ambiguous and vague definitions, which were the underlying basis for the criminal charges brought against Akin, and which has a long and tortuous administrative and judicial history.

The controversy over the ambiguous and vague definitions, which were the underlying basis for the criminal charges brought against Akin, has a long and tortuous administrative and judicial history. *In re OrthoConcepts v. MetraHealth*, Dkt. No. 000-45-1375 (Social Security Administration Office of Hearings and Appeals Decision dated January 3, 1996) the Administrative Law Judge held that an orthotic device similar to that for which Akin is charged with committing fraud was an orthotic device which met the requirements for reimbursement. (*See* Appendix B). Subsequently, the Department of Health and Human Services, Health Care Financing Administration (HCFA) issued its ruling *HCFAR-96-1* (*See* Appendix C) effective September 18, 1996 which "provide[d] clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and quality Control Peer review and related matters". This ruling in effect determined that the orthotic device which was similar to the device sold by Akin's company was not reimbursable. The HCFA ruling (HCFAR-96-1) resulted in a civil law suit entitled *Warder v. Shalala*, (1997 WL 263733, 1997 U.S. Dist. Lexis 7029)[4] which was decided May, 1997 wherein District Judge Lasker held that the orthotic device under the same billing code which Akin had billed was reimbursable stating "[i]t is not necessary, however to decide

4. The decision gives a full history of the underlying controversy as to the ambiguity in the law and regulations and the interpretation given by HCFA.

that the bracing systems do not satisfy the DME[5] definition in order to conclude that *the government cannot use a purported ambiguity created by the devices falling within two coverage categories to classify them as DME.*" [Emphasis supplied] Judge Lasker held that OrthoConcepts was entitled to reimbursement. Judge Lasker's decision was appealed to the United States Court of Appeals for the First Circuit and was reported in *Warder v. Shalala*, 149 F.3d 73 (decided July 27, 1998). The First Circuit held in reversing Judge Lasker's decision that HCFAR 96-1 was an interpretative ruling which did not need notice and comments procedures under the Administrative Procedure Act. Thus, the courts should give deference to the administrative determination.[6] This Court denied certiorari. 119 S. Ct. 1455.

This Court in a civil context has decried the use of retroactive curative cost-limit rule making under the Medicare Act noting that retroactivity is not favored in the law. *Bowen v. Georgetown University Hospital*, 109 S. Ct. 468 (1988). As Mr. Justice Scalia stated in his instructive *Bowen* concurring opinion discussing the distinction of rule making and adjudication "a rule is a statement that has legal consequences only for the future". *Id.* at 476. "Adjudication deals with what the law was; rule making deals with what the law will be". *Id.* at 478 "Quite simply, a rule is an agency statement of 'future effect' *not* 'of future effect and/or *reasonable past effect*' ". Emphasis supplied. *Id.* at 478. "It is important to note that the retroactivity limitation applies only to rule making". *Id.* at 480. Thus, this Court, in the

---

5. DME makes reference to "durable medical equipment."

6. The First Circuit did not reach the question of retroactivity.

context of the case at bar, has impliedly given guidance that the HCFR-96-1 ruling of September 1996 has prospective application only and should not have been used as a basis to criminalize prior sanctioned conduct.

It is with this tortuous administrative and judicial background in dealing with Social Security's vague definitions[7] of orthotic devices and durable medical equipment that Akin became subject to criminal prosecution on May 7, 1997.

In the District Court, Akin moved to dismiss the indictment on the ground that the definition of orthotic devices, which were reimbursable under the Medicare laws, was void for vagueness. The motion was the subject of an evidentiary hearing before the Magistrate Judge. In her Memorandum and Recommendation, the Magistrate Judge acknowledged that the coding for orthotic devices in the Medicare Carrier Claims Manual (L0430) was ambiguous before September of 1996, but recommended that the question of whether the device which was the subject of the indictment was an orthotic device be submitted to a jury.[8] (*See* Appendix D). Petitioner's objections to the Memorandum and Recommendation were overruled by

---

7. The Eleventh Circuit in *Georgia Pacific Corp. v. OSHRC*, 25 F.3d 999, 1005 (1994) has held that where the Secretary of Labor is unable to settle upon a single definition of a critical term or phrase of its own regulations, the regulation is unconstitutionally vague.

8. Contrary to the U.S. Magistrate Judge's recommendation, the question of the ambiguity of a government regulation is a question of law for the judge and not for the jury. *United States v. Upton*, 91 F.3d 677, 683-84 (5th Cir. 1995) The Fifth Circuit refused to address this issue in its unpublished opinion in this case.

implication when the case proceeded to trial without a formal ruling by the District Judge. The Magistrate Judge's factual findings are sustained on appeal unless they are clearly erroneous, and her recommended conclusions of law are reviewed *de novo.*

At the close of the government's case-in-chief, the Petitioner moved for a judgment of acquittal under Rule 29, Federal Rules of Criminal Procedure, which motion was denied. The motion was renewed at the end of all the evidence, and again the motion was denied. Motions for judgment of acquittal are questions of law which are reviewable by this Court *de novo. United States v. Ferguson*, 211 F.3d 878 (5th Cir. 2000); *United States v. Reliford*, 210 F.3d 285 (5th Cir. 2000). Constitutional challenges to government legislative authority are also reviewed *de novo* on appeal. *United States v. Howard*, 220 F.3d 645 (5th Cir. 2000). The court below declined to review Akin's constitutional challenge.

The undisputed evidence at the hearing and at trial showed that at all times charged in the indictment — that is, between June 24, 1992 and June 8, 1993 — there was no directive, order or regulation specifically excluding the device which was the subject of the indictment in this case from coverage as an orthotic under Code L0430. It was not until *after* Dr. Akin had submitted all the claims which were specified in the indictment that an investigation was conducted by the Health Care Financing Administration ("HCFA"). The investigation resulted in a recommendation to the Department of Health and Human Services in April 1994 that more "stringent controls" be instituted to limit payments for orthotic "body jackets," because the applicable code used in billing — L0430 — provided only a "vague"

and "general" description that allowed Medicare suppliers to file claims for other devices. It was not until September 1996 that a HCFA ruling stated a policy regarding the distinction between "orthotics" and "durable medical equipment" and defined an "orthotic device" as a "brace used independently of other equipment." This ruling specifically stated that the purpose of an HCFA ruling is to "provide clarification and interpretation of complex or ambiguous provisions of the law or regulations. . . ." , and was the first official statement by the Department of Health and Human Services relating to the device for which Akin had submitted claims almost four years earlier. In the meanwhile, other regional Medicare carriers had ruled that devices similar to that which was the subject of the charges against Akin, were indeed Medicare-reimbursable orthotics, and two hearing officers had held the same. Contrasted with these belated rulings was the evidence submitted by Akin that *prior* to the marketing of his device, the HCFA issued a letter in 1990 stating the "custom designed orthotic seating and positioning systems . . . may be covered. . . . under the Medicare program". Akin further produced evidence that in 1992 and 1993 some Medicare carriers were allowing payment for similar devices while others were not — a clear indication that no one individual could look at the applicable statutes and regulations and determine what devices could properly be submitted for coverage.

It is the most basic proposition of due process under the Fifth Amendment to the Constitution that a person cannot be held criminally accountable for conduct for which he has no notice of its prohibition. *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). An individual is not required to guess or speculate about whether his conduct is forbidden by law: a legal prohibition must be sufficiently clear that

ordinary persons can understand what conduct contravenes the law. *Kolender v. Lawson*, 461 U.S. 352, 357 (1983). If the terms of the law are so vague that individuals must necessarily guess at its meaning and differ in its application, it does not give "fair warning," and consequently violates the Fifth Amendment Due Process provisions. *United States v. Lanier*, 520 U.S. 259, 266 (1997). If under a law applicable to persons nationwide there is disagreement among those charged with execution of the law as to the appropriateness of payment for a device, the first question to be asked is whether the disagreement stems from ambiguity, vagueness or indefiniteness in the law. In the case at bar, the applicable regulations were treated variably from jurisdiction to jurisdiction for six years, which is a clear sign of ambiguity, vagueness and indefiniteness. It is plain from the regulations themselves defining durable medical equipment and orthotic devices, that the position taken by the government in the case at bar was unduly restrictive, given the broad and inclusive language of the definitions prior to September, 1996.[9]

---

9. The court below declined to address the rule of lenity in the case at bar. However, in *United States v. Marek*, 238 F.3d 310 (5th Cir. February 2, 2001) the court did address this issue, even though it found it not applicable, by stating

> The rule of lenity-a rule of narrow construction rooted in concern for individual rights, awareness that it is the legislature and not the courts that should define criminal activity, and belief that fair warning should be accorded as to what conduct is criminal-applies when, but only when, "after seizing everything from which aid can be derived, the Court is left with an ambiguous statute". . . . The principle behind the rule of lenity is that no one should be forced to speculate whether her conduct is prohibited. *id.* at 322.

The Fifth Circuit has considered, and spoken on, the question of criminal liability in the face of a dispute among proper authorities on the meaning of the law. *United States v. Garber*, 607 F.2d 92 (5th Cir. 1979) (en banc). In that case the defendant, who had an extremely rare blood antibody, had sold her plasma on a contractual basis to a laboratory. She did not report any of the sums received on her tax return, believing that it did not meet the definition of income. There was no definitive court ruling on the issue during the relevant time period, and both sides produced expert testimony at trial to testify to opposing interpretations of the law. The Court held that willfulness is an essential element of tax evasion, but that "[a] tax return is not criminally fraudulent simply because it is erroneous." *Id.* at 97. The Court said that

> The unresolved nature of the law is relevant to show that defendant may not have been aware of a tax liability or may have simply made an error in judgment.

Id. at 98.

In the case at bar, given the government's admissions of vagueness and ambiguity, the basing of a criminal prosecution on a policy statement issued 3 to 4 years *after* the conduct charged in the indictment violates the Due Process Clause prohibitions of the Fifth Amendment. The distinction between an orthotic device and durable medical equipment requires expert analysis and should be highly detailed in the regulations. Otherwise, the legislature's authority to determine forbidden conduct is "impermissibly delegate[d] . . . to policemen, judges and juries for resolution on an ad hoc, subjective basis, with attendant dangers of

arbitrary and discriminatory application." *Grayned v. City of Rockford*, *supra* at 108-09. *Accord*, *Smith v. Goguen*, 415 U.S. 566, 575 (1974). That is precisely what happened in this case: the HHS agent and the prosecutor arbitrarily applied their personal interpretation of the relevant regulations and proceeded with the prosecution on the basis of a theory, which was untested and unresolved by any competent authority, judicial or executive at the time of the conduct which they charged was felonious. Further, there was no evidence that the Medicare carrier, who has no constitutional authority to define criminal conduct, rejected the billings submitted by Akin or his associates, nor gave him any written notice that the specific device in issue in this case would not be covered.

To prove intent to defraud, the government must show that Akin intentionally deceived the Medicare carrier by submitting claims that he knew were false. *See, e.g.*, *United States v. Keller*, 14 F.3d 1051 (5th Cir. 1994); *United States v. Phillips*, 600 F.2d 535 (5th Cir. 1979). Fraud is a matter of deliberate deception. *United States v. Phillips*, *supra* at 537. An individual cannot be guilty of an intentional crime, much less one with the particular burden of proving fraudulent intent, on the basis of a confused, vague and indefinite administrative ruling. While knowledge of legal requirements is a legitimate requirement of anyone dealing with taxpayer funds, those legal requirements should be readily ascertainable and plain in their meaning and application. In this case one cannot be guilty of fraudulently billing devices fully accepted as lawful submissions in another jurisdiction. Further, a Medicare official personally testified for the Petitioner that in her opinion the device was orthotics. Dr. Kaye Jewel, who was Medical Director for Wisconsin Medicare Part B Carrier and medical officer at

the Health Care Financing Administration in Baltimore and Washington, D.C., working on policy statements testified that if there is no specific instruction about a particular device, then "you go with what most fits the function of the code." She further testified that "if it meets the actual descriptors, then it can be coded under L0430." Also included in her testimony was a description of the controversy among state medical directors and within the HCFA as to whether devices similar to Akin's which provided lumbar and/or sacral support were orthotics or some other form of "durable medical equipment" not reimbursable by Medicare which were furnished in a nursing home. "A criminal proceeding is an inappropriate vehicle for pioneering interpretations of . . . law." *United States v. Garber*, *supra* at 100. At the time of the alleged offenses there was no clear interpretation of federal regulations pertaining to orthotic devices such as Dr. Akin claimed his to be.[10] Therefore, he could not, as a

---

10. As Mr. Justice Marshall stated in a statutory context (not in an administrative ruling context) in *Dunn v. United States*, 442 U.S. 100, 112-113 (1979):

> To characterize such an interview as an ancillary proceeding would not only take liberties with the language and legislative history of Sec. 1623, it would also contravene this Court's long-established practice of resolving questions concerning the ambit of a criminal statute in favor of lenity. [citing cases] This practice reflects not merely A convenient maxim of statutory construction. Rather, it is rooted in fundamental principles of due process which mandate that no individual be forced to speculate, at his peril of indictment whether his conduct is prohibited. [citing cases] Thus, to ensure that a legislature speaks with special clarity when marking the boundaries of criminal conduct, courts decline to impose punishment for actions that are not "plainly and unmistakably" proscribed.

matter of law, have intended to defraud the government, which could not decide the question for itself.

Dr. Akin's motion to dismiss and/or motion for judgment of acquittal should have been granted by the trial court.

B. The Petitioner was unconstitutionally sentenced under an increased Offense Level of 29, based upon facts that were not included in the indictment nor proven at trial beyond a reasonable doubt.

The Circuit Court in its unpublished opinion also gave short shrift to Petitioner's constitutional challenge to his sentence by dismissing the argument as having no merit. However, this Court has remanded to the various courts of appeal *Apprendi* issues, similar to the issue raised above.[11]

Petitioner's sentence was unconstitutionally enhanced at sentencing by the District Court based on a preponderance of evidence standard, without the jury's finding of guilt beyond a reasonable doubt on certain facts that were not

---

11. *Burton v. United States*, 121 S. Ct. 32 (2000); *Wims v. United States*, 121 S. Ct. 32 (2000); *Gibson v. United States*; 121 S. Ct. 31 (2000); *Blue v. United States*, 121 S. Ct. 32 (2000); *Brown v. United States*, 2000 U.S. LEXIS 6603; *Clinton v. United States*, 2000 U.S. LEXIS 6605; *Hughes v. United States*, 121 S. Ct. 423 (2000); *Curry v. United States*, 121 S. Ct. 376 (2000); *Hester v. United States*, 121 S. Ct. 336 (2000); *Smith v. United States*, 121 S. Ct. 336 (2000); *Twitty v. United States*, 121 S. Ct. 559 (2000); *Potts v. United States*, 121 S. Ct. 559 (2000); *Meais v. United States*, 121 S. Ct. 559 (2000); *Humphrey v. United States*, 121 S. Ct. 478 (2000); *Knight v. United States*, 121 S. Ct. 478 (2000); *Whitt v. United States*, 121 S. Ct. 423 (2000). *See also Travis Randle v. United States*, 2001 WL 81170 (5th Circuit decision July 17, 2001) where in the Court reversed a sentence on similar ground.

included in the indictment.[12] These enhancements were proposed by the U.S. Probation Officer, argued by the Government and ordered by the court based upon the preponderance of evidence standard outside the jury's finding and after the jury had been discharged.

At sentencing, Petitioner's base offense level was established to be level 23 pursuant to U.S.S.G. § 2S1.1. As such, Petitioner was enhanced four (4) levels for being a leader and organizer based on the preponderance of evidence standard resulting in an approximate 30 months of additional incarceration. Petitioner was neither charged in the indictment for this conduct nor was the jury given any indication under the pleadings that Petitioner was subject to such an enhancement if found guilty. Additionally, Akin's Total Offense Level was enhanced two (2) levels for $328,855.15 for "value of the funds" based on the preponderance of evidence standard resulting in 11 months more incarceration regarding the money laundering counts. This amount of money was not pled in the indictment, as the Government conceded (*See* Government's Addendum Objections to PSI and additionally, U.S. Position Regarding: (1) Defendant's Objections To PSI; and (2) Money Laundering Calculations, filed under seal), nor was the jury given any indication that Akin was subject to such an enhancement if found guilty on this fact.

---

12. The Fifth Circuit on July 19,2001 held in *United States v. Gonzalez*, __ F.3d __, 2001 WL 815606 in deciding an *Apprendi* issue in a drug case that failure to allege an amount of drugs in an indictment, submit it to a jury and prove it beyond a reasonable doubt affected the defendant's substantial rights. The Fifth Circuit in the case at bar failed to address this very same issue which raised by Akin.

Under the Sixth Amendment to the U.S. Constitution, Petitioner's rights indisputably entitled him to a jury determination of guilt on every element of the crime with which he is charged beyond a reasonable doubt. *United States v. Gaudin*, 515 U.S. 506 (1995) *cited* by *Apprendi v. New Jersey*, 530 U.S. 466, 120 S. Ct. 2348 (2000). Further, Petitioner's sentence violates the Sixth Amendment and his due process rights under the Fifth Amendment.

In *United States v. Meshack*, 225 F.3d 556 (5th Cir. 2000) the Fifth Circuit held that *Apprendi* did not clearly resolve whether an enhancement which increases a sentence within the statutory range but which does not increase the sentence beyond that range must be submitted to the jury and proved beyond a reasonable doubt. *Meshack, supra* at 576. Although the Court found the above reading of *Apprendi* plausible, it took the more limited reading of *Apprendi* which requires that a fact be submitted to a jury and proved beyond a reasonable doubt only if that fact, as a formal matter, extends the range of punishment beyond the prescribed statutory maximum. *Appendi, supra* at 2380. Any amount of excess jail time has Sixth Amendment significance. Additionally, the Court in *Meshack* stated that the *Apprendi* majority expressly declined to reverse an earlier opinion allowing a judge to determine by a preponderance whether an enhancement should apply, instead limiting that case's "holding to cases that do not involve the imposition of a sentence more severe than the statutory maximum for the offense established by the jury's verdict." *Meshack, supra*, quoting *Apprendi*, 120 S. Ct. at 2361 n.13 (discussing *McMillan v. Pennsylvania*, 477 U.S. 79 (1986), and noting that it might reconsider the holding in the future). The Fifth Circuit in the case at bar, declined to entertain Petitioner's constitutional challenge to his sentence stating that the District Court committed no error in the sentencing of Petitioner.

Petitioner's sentence was enhanced beyond the statutory maximum permitted and contrary to the dictates of *Apprendi* and therefore was unconstitutional.

CONCLUSION

For the foregoing reasons, certiorari should be granted.

Respectfully submitted,

STEVEN JAY ROZAN
KUNIANSKY, KARAHAN & ROZAN
Attorneys for Petitioner
5051 Westheimer
Suite 700
Houston, Texas 77056
(713) 627-3608

APPENDIX A — PER CURIAM OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT DATED AND FILED MAY 16, 2001

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 00-50140

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

VERSUS

CHARLES PHILIP AKIN,

Defendant-Appellant.

Appeal from the United States District Court
For the Western District of Texas

(SA-97-CR-131-1-HFG)

Before JONES, DeMOSS, and BENAVIDES, Circuit Judges.

PER CURIAM:*

Defendant-Appellant Charles Philip Akin appeals his conviction and sentence for conspiracy to defraud the United

---

* Pursuant to 5TH CIR. R. 47.5, the Court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIR. R. 47.5.4.

States, in violation of 18 U.S.C. § 371; mail fraud, in violation of 18 U.S.C. §§ 2, 1341; money laundering, in violation of 18 U.S.C. § 1956(a)(1)(A)(i); and submitting false claims, in violation of 18 U.S.C. §§ 2, 287. Finding no reversible error, we affirm.

Akin is a dentist, who engaged in the medical supply business from 1991 to 1993. He manufactured a type of wheelchair cushion costing $45 that he marketed to nursing homes as an "orthotic" device reimbursable by Medicare. To this end, Akin became a Medicare provider and received $1,289 per device.

Ultimately, the government indicted Akin and two other defendants[2] in connection with the filing of false claims with Medicare. Under the Medicare program, Medicare providers are furnished with a handbook dealing with the billing of medical equipment supplies and periodically receive newsletters discussing covered and non-covered supplies and services. To obtain reimbursement, a health care supplier submits claims to Medicare carriers on a standardized form, commonly referred to as the HCFA-1500 Form. That form requires the use of a standardized code to define the service or product for which reimbursement is requested, and health care suppliers have the responsibility of accurately identifying the service or product administered to recipients. According to the government, Akin billed his wheelchair cushion under Code L0430, which pertained to items qualifying as "TLSO [Thoracic Lumbar Sacral Orthotic], anterior-posterior-lateral control (body jacket), with interface

2. The other two defendants are not a part of this appeal.

material, custom fitted," notwithstanding the fact that he knew that his product was not an orthotic device, but a non-reimbursable wheelchair cushion.

The jury convicted Akin on all counts of the indictment, and among other things, he was sentenced to 87 months of imprisonment, substantially less than the statutory maximum. This appeal followed.

On appeal, Akin raises several points of error. First, he contends that the indictment should have been dismissed because the basis for those charges was a vague and indefinite Medicare claims code, which failed to give him fair notice of the illegality of his conduct. Next, Akin maintains that the individual or cumulative error of the district court in admitting certain lay testimony, in denying his motion to suppress, and in refusing his proposed jury instructions mandates reversal of his conviction. Finally, he asserts that his sentence violated ***Apprendi v. New Jersey***, 120 S. Ct. 2348 (2000), because it was enhanced based on facts that were not included in the indictment nor found by a jury beyond a reasonable doubt.

After having the benefit of oral argument and thoroughly reviewing the briefs, the record excerpts, and pertinent portions of the record, and the applicable law, we conclude that the district court did not commit any reversible error with respect to the points raised by Akin. Accordingly, the judgment of conviction is **AFFIRMED.**

APPENDIX B — DECISION OF THE SOCIAL SECURITY ADMINISTRATION OFFICE OF HEARINGS AND APPEALS IN *ORTHOCONCEPTS v. METRAHEALTH* DATED JANUARY 3, 1996

In re

OrthoConcepts

v.

MetraHealth

Social Security Administration Office of Hearings and Appeals Decision, Dkt. No. 000-45-1375, Jan. 3, 1996.

* * *

STEWART, Administrative Law Judge: This case is before the Administrative Law Judge on a request for hearing filed by the appellant's representative, the Kelly Law Firm of Atlanta, Georgia, on September 5, 1995. The hearing was held on December 12-13, 1995, in Falls Church, Virginia. The appellant was represented at the hearing by attorneys James P. Kelly and Stephen C. Petrovich. Testifying at the hearing were Kenneth M. Greene, Certified Orthotist and President of OrthoConcepts; Richard J. Nobbe, Vice President of Clinical Services, OrthoConcepts; Gerald I. Blank, M.D., former Medical Director of a major Medicare Part B carrier and James C. Russ, Certified Orthotist and Professor of Orthotics at Northwestern University.

The Administrative Law Judge has carefully considered all the testimony presented at the hearing, the documents

identified in the record as exhibits, the video and slide presentations, the display of the medical devices at issue, the arguments presented and the briefs filed.

ISSUE

The first issue before the Administrative Law Judge is whether the orthotic devices the appellant sold to multiple catastrophically crippled beneficiaries are "braces" and therefore eligible for coverage under Part B of Title XVIII of the Social Security Act (Act), or if the devices are "wheelchairs" or "wheelchair seating systems" and are therefore not eligible for coverage under the durable medical equipment (DME) provisions of Part B because the beneficiaries reside in skilled nursing facilities (SNFs).

The second issue to be decided is whether the appellant is liable for a Medicare overpayment in the amount of $2,149,112.91 because the Carrier determined that the devices sold by the appellant are wheelchairs or wheelchair seating systems and were therefore not eligible for coverage under Medicare's DME guidelines because the beneficiaries reside in SNFs.

DECISION

It is the decision of the Administrative Law Judge that the orthotic devices the appellant sold to multiple beneficiaries are orthotic "braces" and not wheelchairs; and are therefore eligible for coverage under the provisions of Title XVIII of the Act because the devices are used for the purpose of supporting a weak or deformed body member or

to restrict or eliminate motion in a diseased or injured part of the body. Payment should be made for those devices for which payment was denied by the Carrier. The undersigned also finds that the appellant is not liable for any Medicare overpayment because payment was correctly made for the orthotic braces initially reimbursed by the Carrier under the L-Codes billed by the appellant.

EVALUATION OF THE EVIDENCE

The appellant is a company that provides general orthotic management and treatment to catastrophically crippled patients who reside in SNFs (Appellant's ALJ hearing brief, pages 2-5). These patients are generally elderly persons with chronic disease and multiple impairments, i.e., strokes with resulting paralysis, crippling arthritis, Alzheimer's, Parkinson's, osteoporosis, as well as other debilitating neuromuscular diseases. These debilitating conditions render these patients immobile and confined to either a chair or a bed. This immobility causes secondary complications, including spasticity, the development of pressure sores, multisited contractures, musculoskeletal deformities, circulatory problems such as phlebothrombosis and pulmonary embolism, and both respiratory and urinary infections.

Taking into account an individual patient's disease(s) and/or injury(ies) as well as all other medical factors which may impact on the treatment of the patient's resulting biomechanical deficits, the appellant provides custom fabrication and fitting of orthotic braces. These orthotic braces provide: (1) relief of pain by restricting or limiting

motion or weight bearing; (2) immobilization and protection of weak musculoskeletal segments; (3) reduction of axial load; (4) retardation of the progression of deformity; and (5) improvement of function.

On or about December 22, 1994, the Carrier notified one of the appellant's seven subsidiary companies, New York Therapeutic Technologies, Inc. (NYT), that it was suspending its Medicare payments because of possible "fraud and/or wilful misrepresentation" regarding claims NYT submitted for supplying orthotic braces to multiple beneficiaries in SNFs. Specifically, the Carrier accused NYT of billing for orthotic braces when in actuality it was providing wheelchair seating systems to the beneficiaries. On April 13, 1995, the Carrier notified NYT that it was liable for an overpayment in the amount of $1,251,335.97 for claims filed and reimbursed during 1994 and 1995. On March 30, 1995, the Carrier notified another of the appellant's subsidiary companies, Massachusetts Therapeutic Technologies, Inc. (MAT), that it was suspending its Medicare payments for the same reasons as mentioned in the case of NYT. On April 13, 1995, the Carrier notified MAT that it was liable for an overpayment in the amount of $897,776.94 for the years 1994 and 1995.

At the fair hearing level, the hearing officer agreed with the Carrier's determination that the appellant was supplying the beneficiaries with wheelchair seating systems with attachments because the orthotic braces were designed to fit into a wheeled base in order for the beneficiaries to be transported within SNFs. The hearing officer agreed with the appellant's contention that the orthotic devices were

"braces", however, since the braces could not function independently without attachment to a wheeled frame made by the appellant they should be classified as wheelchairs under Medicare's DME guidelines. The hearing officer said that since items of DME are not covered by Medicare when they are primarily used in a SNF, the devices sold by the appellant were not eligible for coverage under Medicare Part B. The hearing officer upheld the Carrier's overpayment determinations and the denial of any additional payments for the orthotic "braces" at issue. In its ALJ hearing brief, the appellant in footnotes 11 and 12 claims that NYT and MAT account for over 74% of the appellant's total revenues for all seven of the sister subsidiaries, and that there is a total of $829,223.22 for claims submitted by these two subsidiaries that have been denied payment by the Carrier.

Section 1834(j)(2)(B) of the Act requires suppliers of medical equipment to submit with a claim for coverage of items of medical equipment, a "certificate of medical necessity" (CMN) completed by a beneficiary's physician. The CMN submitted with the claim must contain information required by the Carrier to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Section 1861(n) and 1861(s)(6) of the Act provide for Medicare coverage of items of DME when determined to be medically reasonable and necessary. DME is defined under the regulations as "equipment which: (1) can withstand repeated use; i.e., could normally be rented, and used by successive patients; (2) is primarily and customarily used to

serve a medical purpose; (3) is generally not useful to a person in the absence of an illness or injury; and (4) is appropriate for use in a patient's home" (42 *Code of Federal Regulations* (CFR) 414.202 and Section 2100.1 of the MCM and Section 60-9 of Health Care Financing Administration's Medicare Coverage Issues Manual (CIM)).

Under Section 1861(n) and Section 410.38(b) of 42 CFR, a "skilled nursing facility" as defined in Section 1819(a)(1) of the Act may not be considered a patient's home for the purpose of coverage of items of DME. A skilled nursing facility is defined as an institution which is primarily engaged in providing skilled nursing care and related services for residents who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons, and is not primarily for the care and treatment of mental diseases.

Section 1861(s)(9) of the Act and Section 414.202 of 42 CFR authorize Medicare coverage of leg, arm, back, and neck braces, including replacements if required because of a change in the patient's physical condition. Orthotic devices such as braces are paid by Medicare Carriers according to Medicare fee schedule guidelines as set forth under Section 414.228 of 42 CFR.

Section 2133 of the MCM states that leg, arm, back, and neck braces are covered when furnished incident to physicians' services or on a physicians' order. Braces include rigid and semi-rigid devices which are used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.

Appendix B

Section 1862(a)(1)(A) of the Act excludes from coverage any expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

After careful consideration of the facts, testimony and the relevant Medicare regulations pertaining to this case, the Administrative Law Judge concludes that the orthotic devices provided by the appellant are "braces" under Medicare regulations, and therefore payment may be made under Part B of the Act for the braces the appellant provided to the beneficiaries. The testimony of the expert witnesses, audio-visual presentations and orthotic demonstrations presented in the hearing provided conclusive evidence that the orthotic devices are "braces as defined in Section 2133 of the MCM. The undersigned also finds that the seven separate L-Codes used by the appellant in billing Medicare for these orthotic braces reflect the nature of the services rendered under the Health Care Financing Administration's coding system.

The evidence and testimony rendered at the hearing clearly indicate that the appellant's orthotic devices are "braces" within the definition given by Section 2133 of the MCM. The appellant's devices are fabricated from rigid and semi-rigid materials and utilize bands, uprights, joints, and straps (Appellant's ALJ hearing brief at p.11). The materials used in a brace depend on the patient's size, the need for flexibility, rigidity, long term durability and the expected demands the patient will place on the brace (*Id.* at 11). The evidence and testimony clearly indicated that the appellant's orthotic devices support weakened or deformed body

members or restrict or eliminate motion of those body members as required under Section 2133. Furthermore, the appellant's devices are supplied to patients pursuant to a physician's prescription as required by Section 1834(j)(2)(B) of the Act, and the devices appear to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member as required by Section 1862(a)(1)(A) of the Act.

The evidence and testimony presented at the hearing also show that the fact that the orthotic devices are attached to wheeled frames does not change the primary function of these devices, nor does the wheeled frame make these devices DME as defined in Section 60-9 of the CIM. Section 60-9 lists four requirements that must be satisfied in order for medical equipment to be classified as DME. DME must (1) be able to withstand repeated use; must (2) primarily and customarily be used to serve a medical purpose; must (3) generally not be useful to an individual in the absence of an illness or injury; and (4) is appropriate for use in the home. The appellant's orthotic devices do not meet two of these four requirements.

I am persuaded by the testimony of James C. Russ, a certified orthotist and a professor of orthotics at Northwestern University. Dr. Russ, who has taught orthotics for many years, visited the appellant's facility and, although initially skeptical, came to the conclusion that the devices were braces. Indeed, he praises them as superior to other products currently on the market which utilize straps and buckles, which patients find uncomfortable and which care givers find difficult to use. He noted that the orthotic devices at issue

are custom-fitted and crafted for individual patients, and are not designed for repeated use by successive patients. The orthotic devices designed by the appellant are made for patients who are catastrophically crippled and who reside in SNFs. The catastrophic nature of their afflictions requires full time nursing care, which is normally found only in long term care facilities. The complexity of design and use of the appellant's braces do not make them appropriate for use in a beneficiary's home as required in Section 60-9. The evidence is clear that the appellant's orthotic devices are in fact braces and not items of DME, and the wheeled frames attached to the braces serve an incidental function in relationship to the orthotic purpose of the appellant's devices.

I was further persuaded by the testimony of Gerald I. Blank, MD, who until recently was medical director of a large Part B carrier. In this capacity, he reviewed and commented upon claims for reimbursement, including claims for durable medical equipment. Dr. Blank testified that the devices in question had been properly coded by the appellant, using the separate "L" codes notes previously.

FINDINGS

After a careful consideration of the entire record, the Administrative Law Judge finds that:

(1) The appellant sold orthotic devices which are "braces" as defined in Section 2133 of the MCM to multiple catastrophically crippled beneficiaries who reside in SNFs.

Appendix B

(2) The fact that the orthotic devices are attached to a wheeled frame does not make them "wheelchairs" as defined under the DME provisions of Section 60-9 of the CIM.

(3) The L-Codes used by the appellant in billing Medicare for these orthotic devices accurately reflect the nature of the services rendered to each of the beneficiaries listed in the files.

(4) The amount in controversy is over $500.00.

DECISION

It is the decision of the Administrative Law Judge that the orthotic devices sold by the appellant to beneficiaries residing in skilled nursing facilities were in fact "braces" and are therefore eligible for coverage under the Medicare Part B provisions of Title XVIII of the Social Security Act. Therefore, the Carrier is directed to make payment under the Medicare fee schedule for all outstanding claims the appellant has submitted for these orthotic devices, and the Carrier's previous overpayment determinations are hereby reversed.

APPENDIX C — RULING NO. 96-1 OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION DATED SEPTEMBER 18, 1996

HCFA Rulings

Department of Health and Human Services
Health Care Financing Administration

Ruling No. 96-1

Date September 1996

HCFAR – 96-1 SEPTEMBER 1996

HCFA Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and quality Control Peer review, and related matters.

HCFA Rulings are binding on all HCFA components, its intermediaries and carriers, including carrier hearing officers, the Provider Reimbursement Review board, the Medicare Geographic Classification Review board, the Departmental Appeals board, and administrative law Judges who have Medicare appeals. These Rulings promote consistency in interpretation of policy and adjudication of disputes.

This Ruling states the policy of the Health Care Financing administration regarding the distinction between The statutory benefits of "orthotics" and "durable medical

equipment" under Medicare Part B. The distinction may have an effect on the Medicare approved amount of payment and is necessary in those instances where items are furnished in skilled nursing facilities that meet the definition in section 1819(a)(1) of the Social Security Act (the Act) or hospitals due to the express exclusion from part B coverage of durable medical equipment when used in a hospital or skilled nursing facility.

The Ruling clarifies that the "orthotics" benefit in section 1861(s)(9) of the Act, insofar as braces are concerned, is limited to leg, arm, back, and neck braces that are used independently rather than in conjunction with, or as components of, other medical or non-medical equipment. It also clarifies that accessories used in conjunction with, and necessary for the full functioning of, durable medical equipment fall under the durable Medical equipment benefits category. Finally, the Ruling provides several examples that illustrate the application and scope of these two terms.

Medicare Program

Medicare Supplementary Medical Insurance (Part B)

CLARIFICATION OF THE TERMS "ORTHOTICS," "BRACES," AND "DURABLE MEDICAL EQUIPMENT" UNDER MEDICARE PART B

HELD: The "orthotics" benefit described in section 1861(s)(9) of the Social Security Act, insofar as braces are concerned, is limited to leg, arm, back, and neck braces that are used independently, rather than in conjunction with, or

as components of, other medical or non-medical equipment. It is also held that leg, arm, back, and neck braces used in conjunction with, and necessary for the full functioning of, durable medical equipment are accessories to the durable medical equipment and, hence, subject to the requirements of section 1861(n) of the Social Security Act.

CITATIONS: Sections 1834(a)(4) and (h) and 1861(n) and (s)(9) of the Social Security Act (42 U.S.C. 1395m(a)(4) and (h) and 1395x(n) and (s)(9); and 42 CFR 414.202.

BACKGROUND

The Medicare program's long-standing policy has been to limit payment for "orthotics" under Medicare Part B to leg, arm, back, and neck braces that are stand-alone devices used independently of other kinds of medical equipment. Recent decisions issued by administrative law judges and Medicare carrier hearing officers have, however, diverged from this policy and have interpreted section 1861(s)(9) of the Act, insofar as braces are concerned, as encompassing all devices that serve to support or restrict motion in a part of the body, even if the devices may not reasonably be used on their own and are primarily intended to be used with other equipment. The purpose of this Ruling is to provide clarification and guidance regarding the scope and meaning of the statutory benefits for "orthotics" and "durable medical equipment."

ORTHOTICS

Section 1834(h) of the Social Security Act (the Act) provides for payment of "orthotics and prosthetics" as described "in

section 1861(s)(9)[.]" Section 1861(s)(9) of the Act in turn lists only the following:

> (9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition[.]

In light of this limited statutory language, we defined "orthotic devices" in 42 CFR 414.202 of our regulations, which states in pertinent part:

> Prosthetic and *orthotic devices means* —
>
> * * * * *
>
> (3) *Leg, arm, back, and neck braces*, and artificial legs, arms, and eyes , including replacements if required because of a change in the beneficiary's physical condition. (Emphasis added).

DURABLE MEDICAL EQUIPMENT

In contrast to the very specific wording of section 1861(s)(9) of the Act, section 1861(n) of the Act employs an open-ended reference to what constitutes "durable medical equipment" by stating that the term "includes" items, such as oxygen tents, hospital beds, and wheelchairs, that may be used in the home. Our definition of durable medical equipment set forth at 42 CFR 414.202, in part, tracks this language by referring in a similarly open-ended manner to medical equipment that can withstand repeated use and is appropriate

for use in the home. In light of the breadth of the durable medical equipment category set forth in the statute and regulation, section 2100.5 of the Medicare Carrier's Manual, Part 3 – Claims Process, "Coverage of Supplies and Accessories," provides that payment for durable medical equipment extends to coverage of "supplies and accessories" that are "necessary for the effective use of durable medical equipment."

SEATING DEVICES AS AN EXAMPLE OF DURABLE MEDICAL EQUIPMENT

Many items, including wheelchairs and hospital beds (both expressly classified as durable medical equipment under section 1861(n) of the Act and section 2100.1 of the Medicare Carrier's Manual, Part 3 – Claims Process, "Definition of Durable Medical Equipment"), support portions of the body. Other items, such as splints or casts (both classified under section 1861(s)(5) of the Act), protect or restrict movement of a portion of the body. None of these items is appropriately classified as a "brace" under section 1861(s)(9) of the Act. (We also generally exclude orthopedic shoes or other shoe inserts or supportive devices for the feet from coverage.)

To the extent that a wheelchair seating system or other equipment may or may not function properly or not achieve its full "therapeutic benefit" without attached components supporting or restricting motion in a body part, the attachments are appropriately viewed as a necessary accessory that is an integral part of the durable medical equipment and is, accordingly, payable as durable medical equipment, provided that the other prerequisites for classification as durable medical equipment are met.

Appendix C

Many seating systems (including wheelchairs) incorporate as integral parts various rests and supporting and positional attachments that are modifications of the seating system and that are intended to be used with the seating system to which they are attached. Section 1861(n) of the Act expressly classifies wheelchairs as durable medical equipment. Furthermore, the legislative history and prior Congressional enactments evidence no intent to classify separately integral components or attachments to seating systems as "braces."

Section 4152(c)(4) of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990), Public Law 101-508, enacted on November 5, 1990, amended section 1834(a)(4) of the Act, governing customized durable medical equipment, to extend coverage to customized wheelchairs that have been "measured, fitted, or adapted in consideration" of a patient's "disability" and including "customized features, modifications, or components" in "accordance with instructions from the patient's physician." The Congress explained that these customized features could "include, but are not limited to" items such as "attachments to convert wheelchairs to one-armed drive," "postural control devices," and "custom molded cushions and inserts or lateral supports." (House Report No. 101-881, 101st Cong., 2d Sess., 1990 USCCAN at 2270.) Thus, ample evidence establishes that the Congress intended sophisticated wheelchairs, including chairs with functional attachments, to be classified in their totality as durable medical equipment.

Even though the Congress was addressing customized wheelchairs, the intent to classify this equipment in its totality as durable medical equipment extends by analogy to ordinary

wheelchairs with attachments. Taken together with the narrow wording of section 1861(s)(9) of the Act, the Congress's treatment of attachments to wheelchairs thus strongly supports the conclusion that a device supporting or restricting motion in a body part but that is an integral part of other equipment is not appropriately classified under the brace benefits category set forth in section 1861(s)(9) of the Act. Our long-standing policy governing the breadth of the durable medical equipment benefits category reflects this congressional intent.

CONCLUSION AND ILLUSTRATIONS

For the reasons set forth above, we therefore conclude that "orthotics" payable under section 1861(s)(9), insofar as braces are concerned, and sections 1834(a) and (h) of the Act are properly limited to leg, arm, back, and neck braces that are stand-alone devices used independently of other kinds of medical equipment. When a device that supports or restricts motion in a part of the body is not generally used, or may not reasonably be used, on its own and is primarily intended to be used with other medical or non-medical equipment payable as durable medical equipment, the durable medical equipment benefits category, and not the brace benefits category, applies.

Following are three examples that illustrate the application and scope of the terms "orthotics" and "durable medical equipment":

Illustration 1. A supplier manufactures and supplies medical devices to individuals who are generally elderly and suffer

from Alzheimer's or other debilitating neuromuscular diseases that have caused them to be nonambulatory, immobile, and confined to a chair or bed. Due to their immobility, these patients may suffer from secondary complications, such as pressure sores, multisited contractures, musculoskeletal degeneration and deformities, and circulatory problems.

Under a physician's order, the supplier furnishes individually fitted attachments designed to be used in conjunction with a chair to seat and position the patient. The attachments, which the supplier labels "orthotic braces," are alleged to position limbs and other body parts properly; restrict motion or weight bearing; immobilize and protect weak musculoskeletal segments; reduce load; retard progression of musculoskeletal deformity; and improve function. The design of the supplier's "orthotic braces" requires them to be attached to the chair frame, and the "orthotic braces" cannot function or be used apart from the chair to which they are attached.

Discussion: Although the devices in question may support or restrict movement in parts of the body, they are not braces within the meaning of 1861(s)(9) of the Act because they are integral parts of a seating system and are not designed or intended to be used apart from the seating system.

Illustration 2. A supplier furnishes what it describes as a lumbar support cushion comprised of a number of attachment straps and front and back cushions molded to fit the patient's body. The device is alleged to supply corrective support and pressure to the back to address postural defects and conditions such as scoliosis (curvature of the spine).

Appendix C

Although capable of being worn separately while standing or lying down, the device is designed to fit into a seated base. In practice, the device is also predominantly worn and used while the patient is seated and is most frequently used by patients who are largely chairbound.

Discussion: Although the device in question may support or restrict movement in parts of the body, it is primarily intended to be used in conjunction with a seat and is comparable to a custom molded cushion or seat insert. The support cushion is accordingly not a brace within the meaning of section 1861(s)(9) of the Act.

Illustration 3. A supplier manufactures a sophisticated hospital bed with motorized sections that may be individually adjusted to position the patient's body and with straps and lateral support devices that provide support and limit movement of the patient's extremities, including limbs. The bed, with its lateral supports, is used with patients who have suffered severe accident trauma, including potential spinal cord injury, and who must be carefully positioned with limited motion to prevent further injury.

Discussion: Although the lateral supports, straps, and motorized sections support and restrict motion in parts of the body, all of these features are integral parts of a hospital bed, which is classified as durable medical equipment, and these components may therefore not be separately categorized as braces under section 1861(s)(9) of the Act.

HELD: The "orthotics" benefit described in section 1861(s)(9), insofar as braces are concerned, and sections

Appendix C

1834(a) and (h) of the Social Security Act is limited to leg, arm, back, and neck braces that are used independently, rather than in conjunction with, or as components of, other medical or non-medical equipment. It is also held that leg, arm, back, and neck braces used in conjunction with, and necessary for the full functioning of, durable medical equipment are accessories to the durable medical equipment and, hence, subject to the requirements of section 1861(n) of the Social Security Act.

EFFECTIVE DATE

This Ruling is effective September 18, 1996.

Dated: September 18, 1996

Bruce C. Vladeck,
Administrator,
Health Care Financing Administration

APPENDIX D — EXCERPTS FROM MEMORANDUM AND RECOMMENDATION OF UNITED STATES MAGISTRATE JUDGE OF THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TEXAS, SAN ANTONIO DIVISION DATED AND FILED MAY 17, 1999

IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TEXAS SAN ANTONIO DIVISION

SA-97-CR-131-OG

UNITED STATES OF AMERICA

V.

CHARLES PHILIP AKIN, TEDDY LEE HENDERSON, and WILLIAM GEORGE GURASICH,

MEMORANDUM AND RECOMMENDATION OF UNITED STATES MAGISTRATE JUDGE

TO: Honorable H. F. Garcia
United States District Judge

* * *

[7] * * *

Motion to Dismiss

A criminal indictment must contain a "plain, concise and definite written statement of essential facts constituting the

offense charged."[10] It must fairly and adequately appraise the defendant of the offenses with which he is charged by listing each prima facie element of the alleged offense, notifying the defendant of the charges against him, and providing a double jeopardy defense against future prosecutions.[11] Defects in an indictment may be raised before trial, but they are also [8] noticed by the court at any time during the proceedings.[12] The sufficiency of an indictment in stating a criminal offense is a question of law for the court, not for the trier of fact.[13]

The due process clause further requires that a penal statute sufficiently define criminal conduct so that an ordinary person can understand what conduct is prohibited.[14] The vagueness doctrine requires that the statute provide adequate notice to one of ordinary intelligence that certain conduct is proscribed so as to avoid erratic and arbitrary law enforcement.[15]

---

10. F.R.Crim.P. 7(c).

11. *See* ***United States v. Flores***, 63 F.3d 1342, 1360-61 (5th Cir. 1995), *cert. denied* 117 S.Ct. 87 (1996); ***United States v. Clark***, 139 F.3d 485, 488 (5th Cir. 1998), *cert. denied* 119 S.Ct. 227 (1998).

12. F.R.Crim.P. 12(b).

13. ***United States v. Mann***, 517 F.2d 259, 266 (5th Cir. 1975), *cert. denied* 423 U.S. 1087 (1976).

14. ***United States v. Daniel***, 813 F.2d 661, 663 (5th Cir. 1987) *citing* ***Kolender v. Lawson***, 461 U.S. 352 (1983).

15. ***Daniel***, 813 F.2d 661, 663 (citations omitted).

Appendix D

Turning to the case at bar, defendants requests dismissal not for insufficiency of the indictment, nor for any vagueness inherent in the false claims or other statutes with which they are charged, but rather for the asserted vagueness of the Medicare definitions by which the jury will determine whether defendants' conduct was fraudulent. Specifically, defendants claim that the criminalization of their conduct violates due process since the HCFA product code definition under which they are accused of filing fraudulent claims was not sufficiently precise. They would like the Court to declare as a matter of law that their conduct could not have constituted fraud.

Some ambiguity undoubtedly existed before 1996 in the definition of Code L0430 found in the Medicare Carriers Claims Manual.[16] However, the statutes under which defendants are charged — false claims, mail fraud and money laundering — are clear. Even if the definition of product code L0430 was ambiguous on a national level, the wheelchair supports for which Defendants were [9] reimbursed by Medicare may still have been excluded from *any* reasonable interpretation of the Code definition. Whether or not the foam supports Defendants supplied can be considered "back braces" is a question of fact that a jury must address. In this regard the jury can consider all the relevant evidence and opinions as to a reasonable interpretation of the Code definition, as well as evidence of defendants' conduct in connection with designing and marketing the product and obtaining the reimbursements.[17]

---

16. *See* Testimony of Ann Berriman, May 10 evidentiary hearing.

17. In a similar case involving a criminal prosecution for fraudulent Medicare claims, the 11th Circuit determined that a (Cont'd)

Defendant himself alludes to this fact issue in his motion: "The code definition during the years in question were [sic] sufficiently general and vague to permit a *reasonable* contention that defendant's fitted body supports met that definition" (emphasis added).[18] The jury must decide if defendant's contentions are reasonable.

For these reasons, I recommend that the motion to dismiss the indictment be denied.

* * *

[13]* * *

SIGNED May 17, 1999.

s/ Nancy Stein Nowak
NANCY STEIN NOWAK
United States Magistrate Judge

(Cont'd)
private insurer's manual definition of consultation (a request for examination by a physician or "other appropriate source") was not unconstitutionally vague as applied to the defendant's conduct when there was ample evidence he had intended to defraud the Government. ***United States v. Hooshmand***, 931 F.2d 725, 732-33 (11th Cir. 1991).

18. Docket Entry No. 42, page 9.

APPENDIX E — CONSTITUTIONAL PROVISIONS, STATUTE AND REGULATIONS INVOLVED

AMENDMENT V

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

AMENDMENT VI

In all criminal prosecutions, the accused shall enjoy the right to a speedy and public trial, by an impartial jury of the State and district wherein the crime shall have been committed, which district shall have been previously ascertained by law, and to be informed of the nature and cause of the accusation; to be confronted with the witnesses against him; to have compulsory process for obtaining witnesses in his favor, and to have the Assistance of Counsel for his defence.

42 U.S.C. § 1395x(s)(9)

(s) The term "medical and other health services" means any of the following items or services:

* * *

(9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition;

* * *

42 C.F.R. §§ 410.100(g)(1)

§§ 410.100 Included services.

* * *

(g) Orthotic device services. These services include —

(1) Orthopedic devices that support or align movable parts of the body, prevent or correct deformities, or improve functioning; . . .

* * *

42 C.F.R. §§ 410.36(a)(3)

§§ 410.36 Medical supplies, appliances, and devices: Scope

(a) Medicare Part B pays for the following medical supplies, appliances and devices:

* * *

Appendix E

(3) Leg, arm, back, and neck braces and artificial legs, arms, and eyes, including replacements if required because of a change in the individual's physical condition.

* * * *